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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,284	02/26/2004	Paul M. Skonezny	GY0111 (NP)	5398
23914	7590	10/16/2006	EXAMINER	
LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/787,284

Applicant(s)

SKONEZNY ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2004 and 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-2, 17-18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing and apparently incorrect in the recitation of "didosine (ddI)", which should apparently be "dideoxyinosine (ddI)".

Claims 1-2, 17-18 and 20 are indefinite in the recitation of "ddA". Abbreviations should be avoided in patent claims unless defined in a previous claim. The recitation of "dideoxyadenosine (ddA)" in at least claim 1 would overcome this rejection.

Claim 20 is incorrect in the recitation of "and" on line 2. There should be only one "and" in series and there is one on line 4.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to "conservative variations" of human adenosine deaminase. There is no guidance given in the instant specification as to what specific residues can be changed to what and still maintain an active enzyme. Without such guidance it is maintained the undue experimentation would be required to practice the instant invention.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farina, et al. (AC). The instant reference teaches in at least the paragraph in column 6, line 1-23, the immobilization of adenosine deaminase on an insoluble support and the reference as a whole teaches that dideoxyinosine (ddI) can be made using adenosine deaminase on dideoxyadenosine (ddA). The concentration of ddA and the pH would have obvious design choices, could have been determined using routine experimentation and would have been obvious to one of ordinary skill in the art, absent unexpected results.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dessouki, et al. (AG) in view of Farina, et al. (AC). Dessouki, et al. teach the immobilization of adenosine deaminase onto an insoluble support and at least in the first column on page 433 teach the activating of the carrier (functionalization) and the activating of the carrier. The secondary reference has been characterized *supra* and teaches the use of immobilized enzyme to produce ddI from ddA. It would have been obvious to one of ordinary skill in the art to immobilize the enzyme as taught by the primary reference and to use it for the purpose taught by the secondary reference.

Claims 1-8 and 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dessouki, et al. (AG) in view of Farina, et al. (AC) and fur-

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ther in view of either of Daddona, et al. (U) or Wiginton, et al. (V). The first two references have been characterized *supra*. Daddona, et al. and Wiginton, et al. teach the sequence of human adenosine deaminase (ADA) as SEQ ID NO:1. It would have been obvious to one of ordinary skill in the art to use the ADA taught by Daddona, et al. or Wiginton, et al. in the method of the instant claims, absent unexpected results.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dessouki, et al. (AG) in view of Farina, et al. (AC), further in view of either of Daddona, et al. (U) or Wiginton, et al. (V) and further in view of Wada, et al. (3AD). The first four references have been characterized *supra*. Wada, et al. teach the preferred codons in different organisms. It would have been obvious to use the teachings of Wada, et al. as to the preferred codons in *E. coli* to change the coding sequence for ADA to those codons, absent unexpected results.

Apparently there were unexpectedly superior results found using human ADA immobilized onto IPS-400, as shown in Table 2. However, none of the instant claims are limited to this embodiment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-

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0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
October 3, 2006